Please add new claim 9.

9. A system for manufacturing build-to-order implantable medical devices, comprising:

an implantable medical device manufacturing assembly facility;

a data center collecting information about inventory status at an implantable medical device implanting institution; and

a manufacturing computer server at an implantable medical device manufacturing site;

the server being in interactive communication with the data center to download inventory status information; and

the server being in communication with the implantable medical device manufacturing assembly facility to initiate manufacture of a build-to-order implantable medical device.

REMARKS

A. Rejections Under §103

Claims 7 and 8 were rejected as being obvious from Duffin (U.S. Patent No. 5,752,976) in view of Colligan (U.S. Patent No. 6,298,443). The examiner relies upon Duffin as disclosing a bi-directional communication system between a programmer for an implantable medical device and a remote expert data center. The examiner admits that Duffin does not disclose storing manufacturing information about the implanted medical device. Colligan is relied upon as teaching the concept of maintaining inventory control. Thus, according to the examiner, combining Duffin and Colligan results in the claimed invention. Further, the examiner contends, without support therefor, that it would have been obvious to one having ordinary skill in the art "to have modified...Duffin to include the concept of a customized build-to-order software image to a computer system taught by Colligan in order to fit customers needs."

B. The Obviousness Rejection Applies An Incorrect Legal Standard

The controlling statutory provision of 35 USC §103 requires, as noted on page 2 of the office action, that the differences between the subject matter sought to be patented and the prior art are such that the subject matter "*as a whole would have been obvious*" to a person having ordinary skill in the art. The legal standard applied in the rejection however only finds that it would have been obvious to modify Duffin to include build-to-order software. Thus, the rejection applies an incorrect legal standard. Even if Duffin could be modified to include a build-to-order software feature, that fact nevertheless does not meet the requirement that it would have been obvious to make the claimed combination. For such a finding, there must be some suggestion or motivation for combining the references. Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999); In re Dembiczak, 175 F.3d 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Nowhere does the rejection identify any suggestion to combine the references. The rejection only finds that Duffin could be modified in accordance with Colligan. The Federal Circuit in In re Dembiczak reversed the Board's decision of obviousness for a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references. Id. at 1000. Absent such a finding, a decision of obviousness cannot stand as a matter of law. Id. Thus, the stated rejection of claims 7 and 8 is in error.

C. The Combination of Duffin and Colligan Fails to Result in the Claimed Subject Matter

Duffin does in fact **not** include a programmer for the implanted medical device. In fact, a distinction of Duffin and an object of its teachings concerns the absence of a

programmer. As pointed out in Duffin, the prior art systems had the patient within short range of a programmer. See column 3, lines 59-66. What Duffin sought to solve was the situation where the patient is out of range of the programmer. See column 3, line 67 to column 4, line 4. Item 20 in Duffin is clearly identified as a patient communications control device (col. 7, lines 22-27) and is basically just a repeater to relay communications to and from the remote base station. Accordingly, the combination of Duffin and Colligan fails to result in the claimed subject matter of claims 7 and 8.

Colligan is characterized as disclosing a "build-to-order" CD ROM. However, Colligan does not disclose a manufacturing facility or process. The CD ROM is custom programmed to permit a user to restore a computer system to a "factory new" software condition. Accordingly, Colligan does not disclose a "build-to-order" manufacturing facility. Thus, the combination of Duffin and Colligan fails to result in the claimed subject matter of claims 7 and 8.

D. Miscellaneous

1. Provisional Double Patenting Rejection

Claims 7 and 8 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting relative to co-pending application serial no. 09/775,262. Applicant will address this rejection when and if it is ultimately made on a non-provisional basis.

2. Drawing Objection

The drawings were objected to because the reference character "60" is shown in both Fig. 2 and Fig. 3 in relation to two different structures. Applicant proposes to

correct the drawing by changing numeral "60" in Fig. 3 to the numeral "63." Attached please find a revised Fig. 3, with the changes marked in red.

E. Conclusion

In consideration of the amendments to the claims and the remarks presented herein, Applicant submits that all pending claims are now in condition for allowance and requests that a notice of allowance issue in due course.

Respectfully submitted,

Date: January 14, 2003

By: _____

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MARKED-UP VERSION OF CHANGES MADE

IN THE SPECIFICATION:

At page 18, lines 4-19, rewrite the paragraph as follows:

Continuing with FIG. 3 and more to the point of its relation to the present invention, we see that the same data as well as the device's model number, serial number, date of implant, and so on are conveyed to system interface 53. At this juncture, the data may be stored (in patient data memory 61) or transmitted/telemetered immediately. The time of transmission is dependent on whether the programmer is or is not connected to phone link 56 or satellite link 55 at the time of implant. Assuming that one of these connections is made at some time during the day, the data from patient data 61 and Internet interface 53 is uplinked to the Internet via phone line modem connection 56 and phone line 59 or telemetric satellite link 55 using data encryption technology for a secure transmission as substantially described in filed application No. 09/431/881, *Method and Apparatus to Secure Data Transfer from Medical Device Systems*, filed November 2, 1999 by Nichols and incorporated herein by reference. Upon reaching Information Network [60] 63, these data are incorporated into the data file containing the complete information relating to the implanting institution, for billing purposes and other uses. These same data are also forwarded to that portion of the network computer related to new build orders for manufacturing, which relates to FIG. 4.

At page 18, line 20 to page 19, line 9, rewrite the paragraph as follows:

Turning our attention now to FIG. 4, we see the various steps used during the manufacturing process to ensure that the recently implanted ICD (using the example mentioned above) is replaced as quickly as possible. Once an implant has taken place

at a particular institution the data is available to the Information Network [60] 63 (see FIG. 3), that same network, which is constantly monitoring the "build-to-order" status 72. The network periodically determines whether a device needs to be built 70 for this particular institution. If No, then it continues to monitor for an implant. If Yes, then the implant data is downloaded to the manufacturing database 74. This includes all pertinent data relative to the implanted device. Specifically, these data will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative, and the name of the implanting institution. These data, when received, will automatically initiate a "build-to-order" replenishment to match and replace the standard device(s) implanted at that institution.

At page 20, lines 16-21, delete the following paragraph:

[In the following claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. For example, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts, a nail and a screw are equivalent structures.]

IN THE CLAIMS:

7. (Amended) A medical device inventory and production control system synchronous with various phases of product manufacturing for standard, customized and newly approved, modified/redesigned devices and to stock various consumption hubs including hospitals, sales offices, distributors and sales representatives on a just-

in-time basis under a build to order and build to replenish production scheme, the system comprising:

a Web-enabled information network being in data communications with manufacturing, shipping/delivery and the various consumption hubs; and

at [lest] least one programmer being in a bi-directional communications link with the Web-enabled information network; and

at least one device implanted in a patient taken out of one of the consumption hubs, and having a wireless communication with the programmer to thereby route device information to the Web-enabled information network.